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EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/737,190

Applicant(s)

SHIBUYA, TETSUO

Examiner

Cheyne D. Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 3-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 12 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. In view of the Appeal Brief filed on February 16, 2005, PROSECUTION IS HEREBY REOPENED. New grounds of rejections are set forth below.
2. The finality of the instant Office Action has been withdrawn.
3. To avoid abandonment of the application, appellant must exercise one of the following two options:
  - (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
  - (2) request reinstatement of the appeal.
4. If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).
5. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
6. Claims 2 and 12 are examined on the merits.

**OBJECTIONS**

7. Claim 12 is objected to because of the phrase "that that" in step (b), line 4. Appropriate correction is required.
8. The abstract of the disclosure is objected to because said abstract has more than 150 words. Applicant is required to submit a new abstract on a separate sheet of paper. See MPEP § 608.01(b).

**CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH**

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
11. Claim 2, step (b) (i) and (ii), recites the limitation of “different complementary variable” which causes said claim to be vague and indefinite. For example, Applicant discloses “the A and T or the G and C of DNA complement each other...” Further, one of skill in the art would have attributed the customary and ordinary meaning of “relating to the specific pairing of the purines and pyrimidines between strands of a DNA or an RNA molecule” to the term complementary. However, the claim is directed to determining “different complementary variable”; therefore, said claim is not clear as to what criteria are being used to determine “complementary variable” or “different complementary variable.” Clarification of the metes and bounds is required. The same issue is present in claim 12 as directed to the limitation of “complementary.”

**LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode

contemplated by the inventor of carrying out his invention.

13. Claims 2 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining complementary strands of a DNA or an RNA molecule, does not reasonably provide enablement for determining the “complementary variable.” The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.
14. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.
15. For example, Applicant exemplifies the claimed method for a gene sequence wherein “the A and T or the G and C of DNA complement each other...” (page 4). Further,

one of skill in the art would have attributed the customary and ordinary meaning of “relating to the specific pairing of the purines and pyrimidines between strands of a DNA or an RNA molecule” (dictionary.com) to the term complementary. However, the claim is directed to “complementary variable.” The specification does not provide clear guidance or working examples which would enable one of skill in the art to determine a “complementary variable.” Therefore, one of skill in the art would require undue experimentation to predictably practice the claimed method.

### **CLAIM REJECTIONS - 35 USC § 101**

16. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

17. Claims 2 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter.

18. It is noted that the limitation of “array” has been reasonably construed as “a rectangular arrangement of quantities in rows and columns, as in a matrix” (dictionary.com).

19. Claims 2 and 12 are rejected because the claimed subject matter is directed to a mathematical algorithm. The claimed invention as recited by claims 2 and 12 is nonstatutory because the claimed invention is specifically directed to the manipulation of a mathematical array. Therefore, the claimed invention being limited

to an abstract idea such as a mathematical array is not patentable (MPEP § 2106 (IV)(B)(1)).

### **CONCLUSION**

20. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.
21. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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22. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.
23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.
24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly /CDL  
5/25/05

Ardin H. Marschel  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER  
5/31/05